IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION

UNITED STATES OF AMERICA,

ex rel. ROSEMARIE M. BOOZE AND

CHARLES F. MACTUTUS,

Plaintiff,

v.

UNIVERSITY OF SOUTH CAROLINA,

THOMAS COGGINS,

AND

JUN ZHU.

Defendants.

Civil Action No. 3:16-cv-183

Filed Under Seal Pursuant to
31 U.S.C. § 3730(b)(2)

JURY TRIAL DEMANDED

COMPLAINT

1. Relators Rosemarie M. Booze and Charles F. Mactutus bring this action on behalf of the United States of America under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-33, against Defendants University of South Carolina ("USC"), and Jun Zhu, M.D., Ph.D. ("Zhu") to recover losses sustained by the Public Health Service ("PHS"), the National Institutes of Health ("NIH"), the National Science Foundation ("NSF"), and other federal agencies responsible for administering scientific research grants.

CHD03580

I. Introduction

2. The NIH is the primary federal sponsor of medical and behavioral research in the United States. NIH grants are selective and highly competitive; 2014 statistics indicate that the award rate for NIH grant applications was approximately 17%.[1]

3. USC is successful in obtaining NIH funding. Since January 1, 2012, USC obtained over $165 million in NIH funding.[2]

4. The facts below demonstrate that USC betrayed the trust of NIH and the people of the United States in several ways. First, the evidence clearly demonstrates that Jun Zhu, one of USC's "rising stars," falsified and/or fabricated the results of his behavioral studies involving nicotine exposure in rats. These falsified and fabricated results were used in publications, specific grant applications, and progress reports.

5. More importantly, USC betrayed the trust of NIH by looking the other way and refusing to conduct an impartial investigation of Jun Zhu's research misconduct. Even after being criticized by the U.S. Health and Human Services ("HHS") Office of Research Integrity ("ORI"), USC performed a second defective investigation with conflicts of interest and "cleared" Jun Zhu again. This occurred because USC intentionally placed the inquiry in the hands of administrators and researchers with conflicts of interest – direct ties to Jun Zhu and his research.

6. As a result of Jun Zhu's research misconduct and the USC administration's refusal to abide by their administrative, regulatory and statutory responsibilities, Jun Zhu and USC violated the False Claims Act by knowingly submitting false statements with the NIH in claims for payment.

[1] http://nexus.od.nih.gov/all/2015/06/29/what-are-the-chances-of-getting-funded/
[2] NIH Reporter, available at: https://projectreporter.nih.gov/reporter.cfm

II. Jurisdiction and Venue

7. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 and 31 U.S.C. §§ 3732(a) and 3730(b).

8. This Court has personal jurisdiction of the Defendants under 31 U.S.C. because Defendant USC can both be found in and transact business in the Western District of North Carolina. Among other things, USC transacted business at its Darla Moore School of Business campus in Charlotte, North Carolina as well as solicited and enrolled students in this District.

9. Venue is proper in this judicial district under 31 U.S.C. § 3732(a) because, at all times material and relevant hereto, Defendant USC transacted business in the Western District of North Carolina.

10. Relators' claims and this Complaint are not based on allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the government is already a party, as enumerated in 31 U.S.C. § 3730(e)(3).

11. To the extent that there has been a public disclosure unknown to the Relators, they are the "original source" and meet the requirements of § 3730(e)(4)(B). Relators have direct and independent knowledge of the information upon which the allegations are based, have added substantially and materially to any publicly disclosed information, and they have voluntarily provided this information to the government, prior to filing this action under seal, as required by 31 U.S.C. § 3730(b)(2), before publicly proceeding with this action.

III. Parties and Other Key Players

A. Rosemarie M. Booze

12. Booze is a resident of South Carolina. At all times relevant hereto, she was an employee of USC.

13. Booze has been a member of the USC faculty since July 1, 2002. Booze served as the Associate and Interim Vice President for Research at USC from November 1, 2006 until June 30, 2009. She is currently Professor and Bicentennial Endowed Chair in Behavioral Neuroscience at USC.

B. Charles F. Mactutus

14. Mactutus is a resident of South Carolina. At all times relevant hereto, he was an employee of USC.

15. Mactutus has been a member of the USC faculty since July 1, 2002. He is currently Professor of Psychology at USC.

C. University of South Carolina

16. Defendant USC is a public university with its main campus located in Columbia, South Carolina. USC operates the Department of Psychology within its College of Arts & Sciences.

17. USC holds itself out to be a hub of research activity.

D. Jun Zhu, M.D., Ph.D.

18. Zhu is an Associate Professor at the USC College of Pharmacy. Zhu is an employee of USC and holds a cross-appointment as Adjunct Professor in the USC Department of Psychology. Zhu is Adrian Gomez's direct supervisor.

E. Thomas Coggins

19. Thomas Coggins is the Director of the Office of Sponsored Awards Management and Research Compliance at USC at all relevant times.

E. Other Key Players

20. Adrian Gomez, Ph.D., was a graduate student at USC and a co-author with Jun Zhu on several publications containing falsified and/or fabricated research results.

21. Kim Creek, Ph.D., is the Vice-Chair of Drug Discovery and Biomedical Sciences at the USC College of Pharmacy.

22. Randall C. Rowan, Pharm.D., was the Interim-Dean of the USC College of Pharmacy at all relevant times.

IV. Legal Framework

23. The FCA provides, in part, that any person who:

> (a)(1)(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (a)(1)(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> [or]
>
> (a)(1)(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.
>
> Is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990, plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729. For purposes of the FCA,

> [T]he terms "knowing" and "knowingly"—(A) mean that a person, with respect to information—(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud

24. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 and 64 Fed. Reg. 47099 (1999), the FCA civil penalties were adjusted to $5,500 to $11,000 for violations occurring on or after September 29, 1999.

A. The NIH Research Grant Program

25. USC annually receives over $40 million in grant funding from the NIH to perform medical research. USC understood that each grant award was subject to requirements intended to ensure that Federal funds were not only handled and spent responsibly, but were not used to disseminate false or fraudulent research results.

26. The NIH awards grants to research institutions, such as USC, through a competitive application process. Research institutions submit proposals, either individually or in collaboration with fellow research institutions, to investigate and understand the nature of living systems. Each application for grant funding is assigned to a NIH study section comprised of experts in a particular scientific discipline or research area. After thorough peer review, the NIH study section grades each application with an overall impact score based upon the significance of the proposed research, the qualifications of the investigator(s) performing the work, the innovation of the research, the validity of the experimental approach, and the environment of the institution at which the research will take place. The overall impact score determines the priority in which an application will receive funding.

27. If an application is selected for funding, the grantee institution receives a notice of award setting forth the grant number, the recipient institution, the start and end dates of the grant, the total amount of grant funds awarded, and the terms and conditions of the award. The applicable terms and conditions incorporate the provisions of the NIH Grants Policy Statement.

The grantee institution accepts the grant award by drawing down funds on this grant, which binds that institution to perform the proposed research according to the terms and conditions of the award.

28. Each year the grantee institution must submit a "complete and accurate progress report"[3] setting forth the activities and research results from that year. (NIH Grants Policy Statement § 8.4.1.1.) The grantee must "describe the studies directed toward specific aims during the current budget year and the positive and negative results obtained." (PHS 2590 Instructions). The grantee must also report all publications, including manuscripts accepted for publication, that result directly from the grant during that funding year. (PHS 2590 Instructions).

29. Publications are a fundamental component of each NIH grant. Grantees are required to report all publications which directly result from the grant. *See* NIH Notice NOT-OD-08-119, "Reminder Concerning Grantee Compliance with Public Access Policy and Related NIH Monitoring Activities" (Sep. 23, 2008); NIH Notice NOT-OD-12-160, "Upcoming Changes to Public Access Policy Reporting Requirements and Related NIH Efforts to Enhance Compliance." (Nov. 16, 2012) ("All grantees submitting paper PHS 2590 progress reports will be required to provide a My NCBI generated PDF list of publications as part of their progress report.").

30. Under the Consolidated Appropriations Act of 2008, the NIH adopted the Public Access Policy, which requires that all publications in peer-reviewed journals which contain research results funded by NIH grants must be made publicly available within twelve months of publication. *See* 42 U.S.C. § 282c. The NIH Public Access Policy was designed to advance

[3] Depending on the type of grant award, the NIH may require the submission of a yearly Non-Competing Continuation Progress Report (PHS 2590) or a Research Performance Progress Report ("RPPR"). Upon information and belief, the required contents of both forms of progress reports would include the results of the proposed research, both positive and negative, as well as incorporate any publications arising out of the grant award.

science by requiring that all NIH-funded research be reported to the NIH and made available to all researchers, students, and the general public to form the basis for future scientific pursuits.

31. Each grant award is subject to certain general terms and conditions promulgated by HHS which govern the use of grant funds. *See* 45 C.F.R. Part § 75.101(a). Among its other duties, the grantee institution "must disclose, in a timely manner, . . . all violations of Federal criminal law involving fraud . . . affecting the Federal award." 45 C.F.R. § 75.113; *see also* 2 C.F.R. § 200.113. These mandatory disclosures include violations of 18 U.S.C. § 1001(a), which prohibits the knowing and willful falsification, concealment, or covering up "by any trick, scheme, or device a material fact" or the making or using of "any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry."

32. Each grantee institution must also comply with PHS-specific regulations (the "Regulations") governing research misconduct. *See* 42 C.F.R. § 93.102(a). The Regulations define "research misconduct" as:

> fabrication, falsification, or plagiarism in proposing, performing or reviewing research or in reporting research results.
>
> (a) Fabrication is making up data or results and recording or reporting them.
>
> (b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
>
> (c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
>
> (d) Research misconduct does not include honest error or differences of opinion.

42 F.R. § 93.103.

33. "Research misconduct involving PHS support is contrary to the interests of the PHS and the Federal government and to the health and safety of the public, to the integrity of

research, and to the conservation of public funds." 42 C.F.R. § 93.100(a). Thus, the Regulations impose upon grantee institutions, like USC, "an affirmative duty to protect PHS funds from misuse by ensuring the integrity of all PHS supported work." 42 C.F.R. § 93.100(b). This duty entails:

> **(a)** Hav[ing] written policies and procedures for addressing allegations of research misconduct . . .
>
> **(b)** Respond[ing] to each allegation of research misconduct . . . in a thorough, competent, objective and fair manner, including precautions to ensure that individuals responsible for carrying out any part of the research misconduct proceeding do not have unresolved personal, professional or financial conflicts of interest with the complainant, respondent or witnesses;
>
> **(c)** Foster a research environment that promotes the responsible conduct of research . . . discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct . . .
>
> (i) Hav[ing] an active assurance of compliance.

42 C.F.R. § 93.300.

34. The grantee institution's assurance of compliance is a critical component of this duty. An assurance of compliance comprises a certification that the institution (a) has written policies and procedures for responding to and investigating allegations of misconduct, and (b) complies with those written policies and procedures. 42 C.F.R. § 92.301(b). This obligates the grantee institution to establish and maintain policies and procedures according to the Regulations as well as "take[] all reasonable and practical specific steps to foster research integrity" including educating and training its researchers regarding research misconduct as well as actively complying with the institution's own policies and procedures and the Regulations, generally. 42 C.F.R . § 93.302(a). The assurance of compliance also obligates the grantee institution to file an Annual Report on Possible Research Misconduct (Form PHS-6349), which details each

allegation, inquiry, and investigation of research misconduct at the grantee institution during that reporting year. 42 C.F.R. § 302(b).

35. This assurance of compliance is required in order for the grantee institution to receive a grant award, and the PHS is prohibited from awarding grant funds to any institution which does not have an approved assurance of compliance on file with the PHS. 42 C.F.R. § 93.301(a).

B. USC's Duty to Investigate Research Misconduct

36. PHS entrusts each grantee institution, including USC, with the primary responsibility of responding to each allegation of research misconduct.

37. USC's responsibilities under the Regulations are invoked when an allegation of possible research misconduct is made. An allegation may be made through any means of communication, whether an written or oral statement or other form, either to a USC or HHS official. *See* 42 C.F.R. § 93.201.

38. USC had a duty to conduct an inquiry if an allegation (i) falls within the Regulations definition of research misconduct, (ii) involves PHS funds, and (iii) is "sufficiently credible and specific so that potential evidence of research misconduct may be identified." *See* 42 C.F.R. 93.307(a).

39. As soon as an allegation is received, USC must "take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner" before, or simultaneous with, notifying the respondent of the allegation. *See* 42 C.F.R. § 93.307(b).

40. After an inquiry is conducted in accordance with 42 C.F.R. § 93.307, USC must determine whether an investigation is warranted. An investigation is warranted if it is determined that there is a "[a] reasonable basis for concluding that the allegation falls within the definition of research misconduct under this part and involves PHS supported biomedical or behavioral research, research training or activities related to that research or research training, as provided in § 93.102," and if "[p]reliminary information-gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance." See 42 C.F.R. § 93.307(d).

41. Whether or not USC decides that an investigation is warranted, the institution is required to complete an inquiry report that includes all relevant information, as outlined in 42 C.F.R. § 93.309.

42. If at any point in the research misconduct proceeding USC determines that certain special circumstances outlined in 42 C.F.R. § 93.318 are present, USC is required to immediately notify ORI and its funding agencies.

V. Factual Allegations

43. Zhu's research focused in two areas: (i) the role of environmental factors on nicotine dependence; and (ii) the mechanisms by which psychostimulants and HIV-1 viral proteins regulate the human dopamine transporter.

A. Experiments Examining the Role of Environment on Nicotine Dependence

44. To examine the effect of a rat's environment on nicotine dependence, Zhu conducted various experiments in Mactutus' lab using Hamilton-Kinder activity chambers (the "Chambers"). Each Chamber contains an array of photocells that track horizontal and vertical movements of a rat within the chamber. The sum total of all movements in the horizontal plane

represent the rat's Total Horizontal Activity, a means of quantifying the rat's physical activity level.

45. Three groups of rats were housed in different environments: Enriched Condition; Standard Condition; and Impoverished Condition. To control for the rats' exposure to a new environment – namely, the Chambers – each rat was permitted to individually habituate to a Chamber over two sixty minute sessions, each on consecutive days.

46. Twenty four hours after the second habituation session, each rat was allowed to habituate to a Chamber for thirty minutes. This session was followed immediately by an injection of saline control, to control for the effect of an injection, and placed in a Chamber for a sixty minute session.

47. Twenty four hours after the saline control injections, half of the rats from each environmental group were given an injection of saline, the other half were given an injection of nicotine. After the first round of injections, each rat was then placed individually in a Chamber and its Total Horizontal Activity was measured over a sixty minute period. Respective injections of saline and nicotine are continued once daily for fifteen days to allow the rats to adjust, or sensitize, to the effects of nicotine or the saline control. After the injections on the fifteenth day, each rat is again placed in a Chamber, and its Total Horizontal Activity was measured.

48. To analyze the isolated effect of nicotine, the change in Total Horizontal Activity was calculated between the rats injected with saline and those injected with nicotine in each environment. The change in Total Horizontal Activity for each environment are compared on day one and day fifteen to determine the effect of nicotine administration on the rats in differing environments.

49. The Mactutus Lab is the only laboratory at USC that contains these Chambers and, therefore, the only laboratory where Zhu could have performed these experiments.

50. Zhu utilized the Chambers in the Mactutus Lab to perform multiple experiments, commencing on July 23, 2009; July 25, 2009; July 5, 2010; October 2, 2010; July 30, 2011; and October 9, 2011.

B. False and/or Fraudulent Statements in Publications

51. Zhu used fraudulent research results to co-author at least four publications. These publications are attached as **Exhibit A** and incorporated by reference. Each of these publications report false, fabricated, manipulated, and/or plagiarized data, as discussed in greater detail below.

(i) PMID 22952905 – *Environmental Enrichment Alters Nicotine-Mediated Locomotor Sensitization and Phosphorylation of DARPP-32 and CREB in Rat Prefrontal Cortex*

52. In 2009 and 2010, Zhu performed experiments that contributed to the paper entitled *Environment Enrichment Alters Nicotine-Mediated Locomotor Sensitization and Phosphorylation of DARPP-32 and CREB in Rat Prefrontal Cortex*. (Ex. A, at Rel_Booze_00022-34.) This paper was published in PLOS One on August 31, 2012. Zhu was the corresponding author of this paper.

53. This paper made the case that exposure to environmental enrichment results in neuroadaptations in the form of altered activation of DARPP-32 and CREB signaling proteins.

54. Zhu claimed that Figures 3A, 3B, 3C, and 3D contains Total Horizontal Activity data that was collected from experiments performed in the Mactutus lab, as described in Paragraphs 44 through 50, commencing on November 7, 2009, July 5, 2010, and October 2, 2010.

55. Upon information and belief, Zhu never performed an experiment in the Mactutus lab on November 7, 2009. Therefore, Zhu falsified and/or fabricated any Total Horizontal Activity data that he claimed to have obtained as a result of this experiment.

56. Upon information and belief, Zhu did not perform the claimed experiment, as described in Paragraphs 47 through 48, on July 5, 2010. Rather, Zhu merely performed two sixty minute habituation sessions, as described in Paragraph 45, without any subsequent saline or nicotine injections or measurements of Total Horizontal Activity. Therefore, Zhu falsified and/or fabricated any Total Horizontal Activity data that he claimed to have obtained on this date.

57. Zhu appears to have performed the claimed experiment beginning on October 2, 2010. He obtained the Total Horizontal Activity data after the first round of injections on October 5, 2010, and he obtained the Total Horizontal Activity data after fifteen days of sensitization on October 19, 2010. These data differ from the data presented in Figures 3A, 3B, 3C, and 3D.

58. Therefore, Zhu falsified and/or fabricated the research results that are presented as Figures 3A, 3B, 3C, and 3D of this paper.

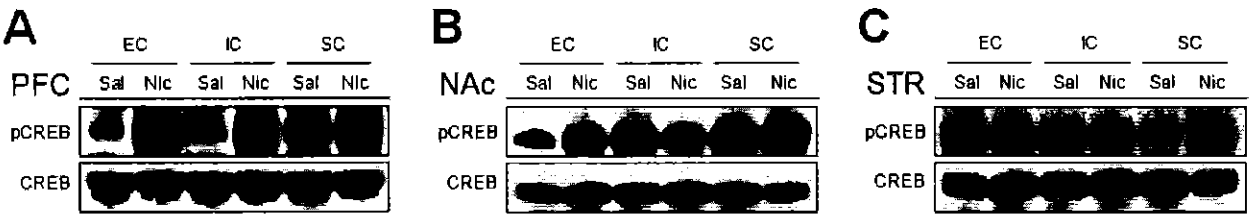
59. Zhu also fabricated the research results presented in Figures 5A, and 5B. These Figures purport to be images of Western blot experiments. Western blots separate proteins in a biological sample into 'bands' according to their size. The amount of each protein in a band is then quantified via densitometric analysis, by examining the size and density of each protein band.

60. These Figures purport to depict the quantity of two proteins – cAMP response element binding protein ("CREB") and phosphorylated CREB ("pCREB") – in specific regions

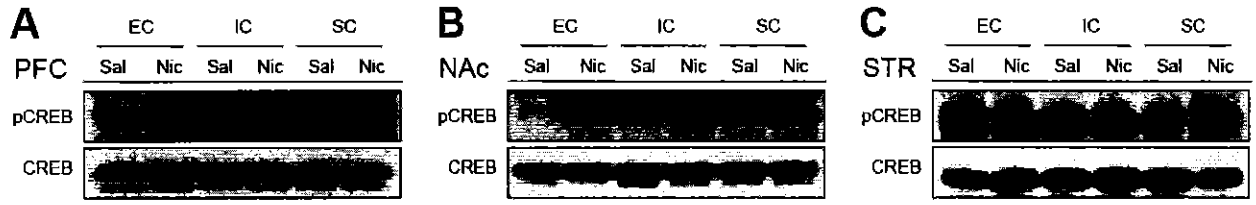
of a rat's brain. Figure 5A purports to show a Western blot of a rat prefrontal cortex. Figure 5B purports to show a Western blot of the rat nucleus accumbens. Figure 5C purports to show a Western blot of the rat striatum.

61. By virtue of their co-authorship on *Environment Enrichment Alters Nicotine-Mediated Locomotor Sensitization and Phosphorylation of DARPP-32 and CREB in Rat Prefrontal Cortex*, Relators received various drafts of this paper, including drafts from May 24, 2012, June 10, 2012, June 12, 2012, and the final draft as published in PLOS One.

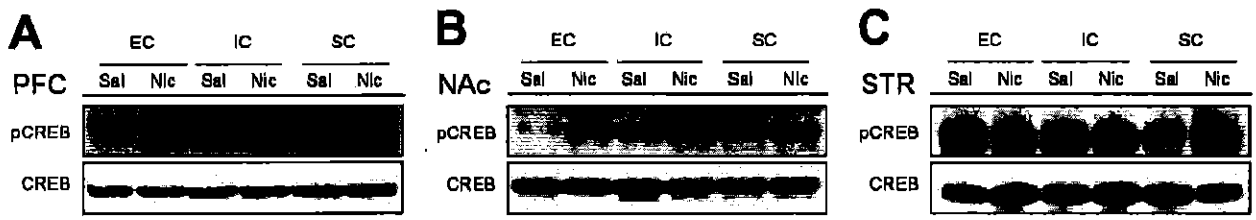
62. The May 24, 2012 draft depicts Figures 5A, 5B, and 5C as follows:



63. The June 10, 2012 and the June 12, 2012 drafts depict Figures 5A, 5B, and 5C as follows:



64. The final draft as published in PLOS One on August 31, 2012 depicts Figures 5A, 5B, and 5C as follows:



65. Examining the various iterations of Figures 5A and 5B reveals that the images published in the final draft of the PLOS One paper differ from the images presented in the earlier drafts. Figure 5A in the May 24, 2012 draft differs from the June 10, 2012 draft, and Figure 5A in the June 12, 2012 draft differs from Figure 5A in the August 31, 2012 final draft. Figure 5B differs between the May 24, 2012 draft and the June 10, 2012 draft. To the extent that Figures 5A and Figures 5B differ from the original images of those Western blots, these Figures contain fabricated and/or manipulated research results.

66. In the alternative, and to the extent that the various drafts contain images of different Western blots in Figures 5A and 5B, Figures 5D and 5E contain false, fabricated, and/or manipulated data. Figure 5D and 5E demonstrate the ratio of the quantity of pCREB to the amount of CREB.

67. This publication cites funding from NIH grants DA 024275 and DA 26721. While not stated in the publication, Zhu stated in an email dated February 9, 2015 that the experiments reported in his publication were also funded by NIH grant P20 GM103499, known as the "South Carolina Idea Networks of Biomedical Research Excellence" (the "INBRE Grant").

(ii) PMID 25328101 – *Effects of environmental enrichment on ERK1/2 phosphorylation in the rat prefrontal cortex following nicotine-induced sensitization or nicotine self-administration*

68. In 2009 and 2010, Zhu performed experiments that contributed to the paper entitled *Effects of environmental enrichment on ERK1/2 phosphorylation in the rat prefrontal cortex following nicotine-induced sensitization or nicotine self-administration.* (Ex. A, at Rel_Booze_00011-21.) This paper was published in the European Journal of Neuroscience in January 2015. Zhu was the corresponding author of this paper.

69. Like the previous publication described above, this publication made the claim that exposure to environmental enrichment triggers a neuroadaptation in rats with respect to nicotine exposure. This publication postulated that the environmental enrichment alters the basal and nicotine-mediated pERK1/2 protein.

70. Zhu claimed that Figures 1A, 1B, 1C, and 1D contains Total Horizontal Activity data that was collected from experiments performed in the Mactutus lab, as described in Paragraphs 44 through 50, commencing on November 7, 2009 and July 5, 2010.

71. Upon information and belief, Zhu never performed an experiment in the Mactutus lab on November 7, 2009. Therefore, Zhu falsified and/or fabricated any Total Horizontal Activity data that he claimed to have obtained on this date.

72. Upon information and belief, Zhu did not perform the claimed experiment, as described in Paragraphs 44 through 50, on July 5, 2010. Rather, Zhu merely performed two sixty minute habituation sessions, as described in Paragraphs 45 and 46, without any subsequent saline or nicotine injection. Therefore, Zhu falsified and/or fabricated any Total Horizontal Activity data that he claimed to have obtained on this date.

73. Zhu falsified and/or fabricated the research results that are presented as Figures 1A, 1B, 1C, and 1D of this paper.

74. This publication cites funding from NIH grants DA024275, DA26721, DA035714, DA021287, P20 GM103641, as well as the INBRE Grant (P20 GM103499).

(iii) PMID 25604666 – *Mutations at Tyrosine 88, Lysine 92 and Tyrosine 470 of Human Dopamine Transporter Result in an attenuation of HIV-1 Tat-Induced Inhibition of Dopamine Transport*

75. Zhu is the corresponding author of *Mutations at Tyrosine 88, Lysine 92 and Tyrosine 470 of Human Dopamine Transporter Result in an Attenuation of HIV-1 Tat-Induced*

Inhibition of Dopamine Transport ("Middle, *et al.* 2015"). This paper was published in the Journal of Neuroimmune Pharmacology on January 22, 2015.

76. Middle, *et al.* 2015 proposes a model by which Tat binds to hDAT and inhibits dopamine ("DA") uptake. The paper reports a computational model that predicts that Tat inhibits hDAT through certain amino acid residues on the hDAT protein, namely tyrosine 88 ("Y88"), lysine 92 ("K92"), and tyrosine 470 ("Y470"). The paper then attempts to validate the computational model through *in vitro* experiments which attempt to isolate the impact of each amino acid residue on the ability of Tat to bind hDAT.

77. The described experiments modified the Y88, K92, and Y470 residues via site specific mutagenesis of wild type hDAT ("WT-hDAT") to yield five mutant hDAT strains: (i) mutation of Y88 to phenylalanine ("Y88F"); (ii) mutation of K92 to methionine ("K92M"); (iii) mutation of Y470 to phenylalanine ("7470F"); (iv) mutation of Y470 to histidine ("Y470H"); and (v) mutation of Y470 to alanine ("Y470A").

78. The effect of mutating each of these amino acid residues was examined by tritiated dopamine ("[^{3}H]DA") uptake assay. Six cell lines, each expressing WT-hDAT or one of the mutant forms of hDAT, were exposed to an excess of [^{3}H]DA to determine the maximum rate – maximal velocity ("V_{max}") – by which each version of hDAT could bind [^{3}H]DA in the presence of Tat. Tat inhibits hDAT from binding [^{3}H]DA. Therefore, hDAT has a lower V_{max} in the presence of Tat. To the extent that a mutation in Y88, K92 , or Y470, increases V_{max} as compared to WT-hDAT in the presence of Tat, that mutation affects Tat's ability to bind and inhibit hDAT.

79. Figure 5A and 5B purports to show the "[e]ffect of Tat or TatCys22 on kinetic analysis of [^{3}H]DA uptake in WT hDAT" and its mutants.

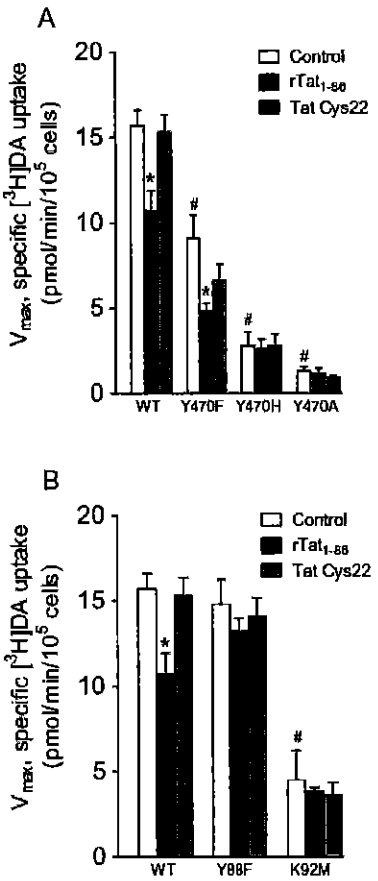


Fig. 5 Effects of Tat or Tat Cys22 on kinetic analysis of [^{3}H]DA uptake in WT hDAT and Tyr470 mutants. a PC12 cells transfected with WT hDAT (WT), Y470F-hDAT (Y470F), Y470H-hDAT (Y470H) or Y470A-hDAT (Y470A) were preincubated with or without recombinant Tat_{1-86} ($rTat_{1-86}$) or Tat Cys22 (500 nM, final concentration) at room temperature for 20 min followed by the addition of 0.05 μM final concentration of the [^{3}H]DA. Nonspecific uptake was determined in the presence of 10 μM final concentration of nomifensine. b [^{3}H]DA uptake in cells transfected with WT hDAT (WT), Y88F-hDAT (Y88F) and K92M-hDAT (K92M) was determined in the presence or absence of Tat Cys22 or $rTat_{1-86}$ (500 nM, final concentration). Data are expressed as means from seven independent experiments ± S.E.M. * $p<0.05$ compared with the respective control values. # $p<0.05$ compared to WT hDAT

80. Describing the results reported in Figure 5A and 5B, Zhu reported that the presence of Tat "decreased the V_{max} of [^{3}H]DA uptake by 32% in WT hDAT . . . and by 47% in Y470F-hDAT." (Middle, *et al.* 2015, at 128.) Zhu went on to report that the presence of Tat had no effect in Y470H-hDAT, Y470A-hDATY88F-hDAT, and K92M-hDAT transfected cells.

81. This publication cites funding from NIH grant DA 35714.

(iv) PMID 25695767 – *Molecular Mechanism of HIV-1 Tat Interacting with Human Dopamine Transporter*

82. Zhu is also an author of *Molecular Mechanism of HIV-1 Tat Interacting with Human Dopamine Transporter* ("Yuan, *et al.* 2015"). This paper was published in ACS Chemical Neuroscience journal on February 19, 2015.

83. Yuan, *et al.* 2015 also proposes a model by which HIV-1 transactivator of transcription ("Tat") binds to human dopamine transporter ("hDAT") and inhibits dopamine uptake. The model proposed in Yuan, *et al.* 2015 is identical to that proposed in Middle, *et al.* 2015. Furthermore, Yuan, *et al.* 2015 describes using the exact same computational and *in vitro* experimental methods as described in Middle, *et al.* 2015.

84. Figures 4A and 4B, reproduced below, report the results of the [^{3}H]DA uptake assay. (Yuan, *et al.* 2015, at E.)

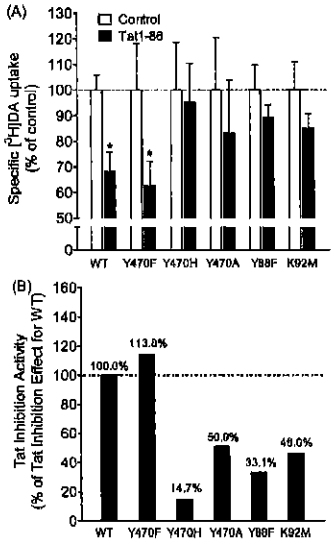


Figure 4. Effects of Tat on the kinetic analysis of [^{3}H]DA uptake by WT-hDAT and its mutants. (A) PC12 cells transfected with WT-hDAT (WT) Y470F-hDAT (Y470F), Y470H-hDAT (Y470H), Y470A-hDAT (Y470A), Y88F-hDAT (Y88F), or K92M-hDAT (K92M) were preincubated with or without recombinant Tat_{1-86} (500 nM, final concentration) at room temperature for 20 min followed by the addition of 0.05 μM final concentration of the [^{3}H]DA. *$p < 0.05$ compared to respective control in the absence of Tat ($n = 4$). (B) The corresponding Tat-induced inhibitory effects on [^{3}H]DA uptake in hDAT mutants were presented as the percentage of the Tat-induced inhibitory effect of [^{3}H]DA uptake in WT-hDAT (100%) at the same concentrations of [^{3}H]DA (0.05 μM) and Tat_{1-86} (500 nM).

85. Zhu reported that the "exposure to Tat_{1-86} significantly decreased [^{3}H]DA uptake in WT-hDAT by 33.0% and Y470F-hDAT by 37.6%; however nearly negligible effects of Tat were observed in Y470H-hDAT, Y470A-hDAT, Y88F-hDAT, and K92M-hDAT." (Yuan, *et al.* 2015, at D.)

86. The "specific [^{3}H]DA uptake" data presented in Figure 4A and 4B of Yuan, *et al.* 2015 is the exact same V_{max} data presented in Figure 5A and 5B of Middle, *et al.* 2015.

87. In particular, the "control" and "$rTat_{1-86}$" groups in Figure 5A and 5B of Middle, *et al.* 2015 are expressed as percent of control in Figure 4A of Yuan, *et al.* 2015. By way of example, the WT-Control (white bar) in Figure 4A of Yuan, *et al.* 2015 represents the percent change in the WT-Control (white bar) in Figure 5A of Middle, *et al.* 2015. Moreover, the WT-Tat_{1-86} (black bar) in Figure 4A of Yuan, *et al.* 2015 represents the percent change in the WT-$r_{Tat1-86}$ (black bar) from the WT-Control (white bar) in Figure 5A of Middle, *et al.* 2015.

88. The research results presented in Figure 4A of Yuan, *et al.* 2015 were appropriated from Figures 5A and 5B of Middle, *et al.* 2015 without appropriate attribution. Under the Regulations, Figure 4A of Yuan, *et al.* 2015 was plagiarized and, therefore, is a product of research misconduct.

89. Figure 4A of Yuan, *et al.* 2015 manipulates and/or changes certain research results presented in Figures 5A and 5B of Middle, *et al.* 2015. Yuan, *et al.* 2015 reports that Tat exposure decreased [^{3}H]DA uptake in the Y470F-hDAT cell line by 37.6.0% whereas Middle, *et al.* 2015 reports that Tat exposure decreased [^{3}H]DA uptake by 47%. Furthermore, Yuan, *et al.* 2015 reports that Tat exposure decreased [^{3}H]DA uptake in the WT-hDAT cell line by 33.0% whereas Middle, *et al.* 2015 reports that Tat exposure decreased [^{3}H]DA uptake by 32%.

90. As the same experiment underlies both Figure 4A of Yuan, *et al.* 2015 and Figures 5A and 5B of Middle, *et al.* 2015, the research results reported in each of these figures should be identical. To the extent that Figure 4A of Yuan, *et al.* 2015 and Figures 5A and 5B of Middle, *et al.* 2015 differ – and to the extent that both publications differ from the 35714 grant progress report, discussed below – these publications report false, fabricated, and/or manipulated data.

91. Figure 4A of Yuan, *et al.* 2015 also omits certain research results presented in Figures 5A and 5B of Middle, *et al.* 2015. In particular, all research results regarding Vmax of the various cell lines incubated with TatCys22 were selectively omitted in Yuan, *et al.* 2015. The omitted research results are depicted as the grey bars in Middle, *et al.* 2015. Under the Regulations, Figure 4A reports falsified research results.

92. This publication reports that it was funded by four NIH grants – R01 DA 035714, R01 DA035552, R01 DA032910, and R01 DA025100 – and NSF grant CHE-111176.

C. False Statements in NIH Grant Documents

93. USC also used these false, fabricated, and/or manipulated research results to seek and obtain payment through the NIH grant system.

94. The interaction among grant applications, grant progress reports, and publications establish that USC made the same false reports of research results to the NIH in grant documents as were made in the publications funded by NIH grants. For each grant, USC was required to report the research results obtained during that year as well as all publications. The false research results in Zhu's publications, therefore, were also reported to the NIH in USC's grant progress reports.

95. By way of example, Zhu published fabricated reports of research results in Middle, *et al.* (2015) and Yuan, *et al.* (2015), as discussed above. These publications state that the research was funded by NIH grant R01 DA035714 (the "35714 Grant"), among others. Thus, the NIH requires USC to report these same fabricated research results in the 35714 Grant progress report as were reported in both Middle, *et al.* (2015) and Yuan, *et al.* (2015). Examining the 2015 Progress Report for the 35714 Grant – NIH grant number 5R01 DA035714-03 reveals that USC, as expected, reported both of these publications as well as the false and/or fabricated research results reported therein.

96. On page 5 of the 2015 Progress Report, Zhu reports that both Middle, *et al.* (2015) and Yuan, *et al.* (2015) as being funded directly from the 35714 Grant.

97. On page 4 of the 2015 Progress Report, Zhu reports: "we examined the pharmacological profiles of [^{3}H]DA uptake in PC12 cells transfected with plasmid DNAs for WT hDAT and these mutants. Results show that, compared to the maximal velocity (V_{max}) values of [^{3}H]DA uptake in wild type (WT) hDAT (15.7 ± 4.6 pmol/min10^5 cells), the V_{max} values were reduced in Y470H (75%), K92M (71%), D381L (64%), and Y470A (90%) but not changed in Y88F, D206L, or Y470F, without detectable changes to the K_m." These data are also reported in Figure 5 of the Middle, *et al.* (2015) paper. However, Figure 5 of Middle, *et al.* demonstrates that the V_{max} value in Y470H mutants were reduced by 81%.

98. On page 5 of the 2015 Progress Report, Zhu reports: "We found that exposure to Tat_{1-86} decreased [^{3}H]DA uptake by 38% in WT hDAT; however, Y470A, Y88F, K92M, D381L, D206L, and H547A, but not Y470F attenuated the Tat-induced inhibition of DA transport . . . ." These data are also reported in Figure 5 of the Middle, *et al.*, paper and Figure 4 of the Yuan, *et al.* (2015) paper. However, Yuan, *et al.* states that "Experimental data (Figure 4A) revealed that,

compared to their respective controls, exposure to Tat_{1-86} significantly decreased [^{3}H]DA uptake in WT-hDAT by 33.0%." Furthermore, Figure 5 of Middle, *et al.* demonstrates that Tat_{1-86} decreased [^{3}H]DA uptake in WT-hDAT by 31%.

99. The above identified reports of research results on pages 4 and 5 of the 2015 Progress Report are false and/or fabricated statements.

100. As exemplified above, USC made the same reports of false and/or fabricated research results to the NIH in the grant documents as were also made in the publications funded by those NIH grants. These grants include, but are not limited to:

a. R01 DA035714;

b. R03 DA024275;

c. R03 DA026721;

d. P20 GM103499, formerly P20 RR016461;

e. RO1 DA021287; and

f. P20 GM103641.

101. Since 2009, USC has submitted these six NIH grants, among others, totalling over $43,390,747, that were directly premised on and/or arose out of Zhu's research misconduct. Each of these grants, and their associated grant documents, are claims for payment under the FCA. *See* 31 U.S.C. § 3729(b)(2).

102. In a similar way, USC caused false claims to be submitted in connection with NSF grant CHE-111176 by submitting false and/or fabricated preliminary data in the grant application and/or progress reports.

D. False Certifications

(i) USC made false certifications in Institutional Assurance and Annual Report

103. USC made false express and/or implied certifications in its Institutional Assurance and Annual Report.

104. USC is required to submit an institutional assurance that (i) it has written policies and procedures in compliance with 42 C.F.R. part 93 for inquiring into and investigating research misconduct, and (ii) it complies with its policies and procedures as well as the requirements of the Regulations. *See* 42 C.F.R. § 93.301(b). Each year, USC submits these assurances in its Institutional Assurance and Annual Report on Possible Research Misconduct, PHS 4349. These assurances are required for USC to receive PHS funding, including NIH grant funds. *See* 42 C.F.R. § 93.301(a).

105. Defendant Coggins supervises the implementation of these assurances and the express certification of these assurances to the government.

(a) USC's policy governing research misconduct

106. USC recognizes that there is a risk of misconduct and fraud inherent in grant funded research. While the purpose of grants are to explore and understand human disease and medical treatments with the ultimate goal of improving public health, research grants also give rise to personal benefits to researchers and grantee institutions.

107. Individual researchers receive a direct financial benefit as these grants often pay their salaries and the costs of running a laboratory. Researchers indirectly benefit by publishing the research results funded by federal grants. The number and impact of these publications promote the researcher's professional reputation and are often a significant factor in professional advancement.

108. Grantee institutions, such as USC, also receive a direct financial benefit from research grants. A portion of each grant award, known as "indirect costs", are diverted away from funding the research project and paid directly to the grantee institution. Indirect costs are, in effect, the price the federal government and taxpayers pay for doing research at that institution. USC currently applies an indirect cost rate of 46.5 percent to its federal grants.[4]

109. With these benefits, researchers and grantee institutions often experience incredible pressure under the research grant feedback loop. Researchers must produce research results to publish scientific papers. These papers are the basis for applying for and obtaining new grants. Under these new grants, researchers are back at square one; they must produce new research to publish papers, and the cycle perpetuates itself. If this cycle breaks down, researchers do not have grant funds to pay their and their employees' salaries. If this cycle breaks down, they do not have funds to publish papers and advance professionally. If this cycle breaks down, grantee institutions, such as USC, do not receive their indirect costs payment.

110. The personal benefits to individual researchers and grantee institutions give rise to perverse incentives that run contrary to the aims of federal grant research. Individual researchers have the incentive to commit research misconduct – to falsify, fabricate, or plagiarize research – in order to produce new research results and new grants to keep the grant funds flowing. Grantee institutions have the incentive to downplay, minimize, and even conceal research misconduct, should it occur, to avoid governmental scrutiny and preserve the flow of grant funds.

111. In recognition of these risks, the Regulations require that each research institution, like USC, have policies and procedures in place to address research misconduct. *See* 42 C.F.R. §

[4] The indirect cost rate for USC during the relevant times was 45% (July 1, 2009 – June 30, 2012) and 46.5% (July 1, 2012 – June 30, 2017).

93.300 (requiring that institutions must "[h]ave written policies and procedures for addressing allegations of research misconduct that meet the requirements of" the Regulations).

112. Effective February 8, 1991, and revised on November 8, 2013, USC issued RSCH 1.00, its policy and procedure governing Misconduct in Research and Scholarship (the "USC Policy") (available at http://www.sc.edu/policies/ppm/rsch100.pdf).

113. USC reviewed its policy for "organization, content and accuracy" in October 2013 but noted that "no substantive revision [was] required." (USC Policy, III.)

114. The USC Policy states that "[t]he University is dedicated to truth in pursuit of knowledge through research and to the transmission of knowledge through teaching. A spirit of mutual respect and a broad trust that all faculty members, students and staff share this dedication to the truth are essential to the functioning of the University." (USC Policy, I(A) (emphasis added).)

115. According to the USC Policy, everyone in the USC community bears responsibility for recognizing and reporting research misconduct: "The integrity of the programs of the University requires that faculty, students and staff be aware of potential misconduct in themselves and in others." (USC Policy, I(A).)

116. USC adopted this Policy in an attempt to comply with the Regulations, to maintain its assurance status, and to remain eligible to receive NIH grant funds. *See* 42 C.F.R. § 93.300(a) (requiring written policies and procedures governing research misconduct); 42 C.F.R. § 93.301(a) (requiring an institution to have an approved assurance on file with Office of Research Integrity ("ORI") to be eligible to receive NIH grant funds).

(b) USC's Policy does not comply with federal regulations.

117. The USC Policy is generally comprised of four sequential steps: (i) action by the division head; (ii) action by the dean; (iii) a limited review by the ad hoc committee; and finally (iv) an investigation by the ad hoc committee.

118. After an allegation of research misconduct is made, the USC Policy refers the allegation to the "division head." (USC Policy, II(B)(1).) "If the division head is personally involved to any degree, then" he must refer the matter to the dean. (USC Policy, II(B)(1).) If not involved, the division head must perform a preliminary inquiry "(a) to exclude frivolous accusations, and (b) to distinguish between misconduct and carelessness and incompetence." (USC Policy, II(B)(1).) At this stage, the person accused of committing research misconduct – the respondent – is notified of the allegation and given an opportunity to respond. (USC Policy, II(B)(1); *see also* USC Policy, II(b)(4) ("In either event, the division head must promptly inform the accused and the accuser of the action taken in the matter.").)

119. "If the division head decides that there are no grounds for a charge of misconduct and that no further inquiry is necessary, a written report of the matter should be submitted to the dean, unless the division head feels that, to protect innocent parties, further communication is inappropriate." (USC Policy, II(B)(2).)

120. "If the division head decides that there is reason to suspect that misconduct has occurred, a report to the dean is mandatory." (USC Policy, II(B)(3).)

121. The USC Policy violates PHS Regulations (42 C.F.R. Part 93) because it permits a "division head" to improperly terminate a research misconduct inquiry for "confidentiality" reasons without complying with the PHS Regulations' requirements to (1) maintain a written record of the inquiry process, and (2) notify ORI that an inquiry took place.

(ii) USC made false certifications in grant applications and grant progress reports

122. USC made false express and/or implied certifications in grant applications and grant progress reports. When submitting an NIH grant application, USC expressly certified "(1) to the statements contained in the list of certifications and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances." *See* SF424 (R&R).

123. The list of express certifications contained in each NIH grant applications includes a certification that: "The institution will comply with the requirements of the PHS regulations for dealing with and reporting possible research misconduct under 42 CFR part 93." (PHS Supplemental Instructions, at III-29.) A tenet of this certification is that the institution "[c]omplies with its own policies and procedures." *See* 42 C.F.R. § 93.301(b)(2).

(a) USC's inquiry into the first allegation of research misconduct made against Zhu.

124. During the afternoon of January 30, 2015, Mactutus placed a telephone call to Coggins regarding Zhu's admission of research misconduct. Mactutus' oral statements during this telephone call constituted an allegation of research misconduct within the meaning of the Regulations. See 42 C.F.R. § 93.201. During that call, Coggins asked the Relators to prepare and submit a report on this alleged research misconduct.

125. Relators prepared and submitted a memorandum, entitled "Admitted Scientific Misconduct of Associate Professor Jun Zhu, M.D., Ph.D." (the "Original Allegation") on February 2, 2015 at 4:57 PM. The Original Allegation raises three specific instances of research misconduct committed by Zhu:

a. Figure 1C of the 2015 Gomez Paper contains the same research results as Figure 3A of the 2012 Gomez Paper;

b. Figure 1D of the 2015 Gomez Paper contains the same research results as Figure 3B of the 2012 Gomez Paper; and

c. Figures 1A and 1B of the 2015 Gomez Paper report the same research results as in Figures 2C and 2D of the 2012 Gomez Paper.

(b) USC failed to properly conduct an inquiry into the first allegation of research misconduct made against Zhu.

126. USC's inquiry into the Original Allegation did not comply with its own policy governing research misconduct, nor did it comply with federal regulations.

127. After receiving the Original Allegation, USC was required to obtain all data or other research records that were relevant to the Original Allegation before notifying Zhu. *See* 42 C.F.R. § 93.307(b). USC, therefore, was obligated to obtain not just the research records that Zhu created in connection with these Figures; USC was obligated to obtain the raw machine-generated data from Mactutus' lab underlying Figure 3 of the 2012 Gomez Paper and Figure 1 of the 2015 Gomez Paper.

128. USC did not obtain the raw machine-generated data from Mactutus prior to notifying Zhu of the allegation of research misconduct against him. Creek and Rowen notified Zhu of the allegation of research misconduct against him on February 18, 2015. Creek and Rowen, however, did not obtain Zhu's research records until February 24, 2015. Therefore, USC failed to comply with its obligations under 42 U.S.C. § 93.307(b).

129. Furthermore, USC did not obtain, nor did it attempt to obtain, the raw machine-generated data at any point prior to issuing the Inquiry Report. During the Relators' March 12, 2015 interview with Creek and Rowen, they discussed whether Zhu actually possessed raw machine-generated data underlying the affected Figures or whether Zhu had fabricated data files. Creek or Rowen asked: "What would we need to see to be absolutely sure that this [the data

produced by Zhu] was original data?" **[28:34]**. Relators responded that Creek and Rowen would have to look at the raw machine-generated data and "in the absence of that its hard to know" whether Zhu fabricated data. **[29:03]**. Creek or Rowen proceeded to ask: "So I'm just thinking in terms . . . he brings us a stack of data, . . . how do we know that that hasn't been altered at all, that's original data." **[29:26]**. Mactutus responded, "The computer [in the Mactutus lab] has the original files with the time and date stamp on them, so you know they are original." Booze continued, "We have the original data on the computer, so everyone should be able to go back to the original data files." **[29:55]**. Therefore, Relators informed USC that they possessed the raw machine-generated data that could be compared to Zhu's data files in order to ascertain whether Zhu had falsified, fabricated, and/or manipulated research results, but USC did not obtain or secure this raw machine-generated data.

130. Knowing that Relators were willing and able to produce the raw machine-generated data to Creek and Rowen for use in the inquiry, USC falsely stated in its Inquiry Report that Relators had no other information to assist in the inquiry besides what was stated in their allegation.

131. Had Creek and Rowen attempted to look at the raw machine-generated data on Relators' computers, they would have known that no raw-machine generated data exists for "Order I from 10/01/2009 of 37 rats with behavioral testing beginning on 11/07/2009." Upon information and belief, Zhu never performed behavioral testing beginning on November 7, 2009. Therefore, any data files produced by Zhu purportedly obtained from this alleged experiment are entirely falsified and/or fabricated.

132. Moreover, had Creek and Rowen attempted to look at the raw machine-generated data on Relators' computers, they would have known that Zhu did not perform the claimed

experiment for "Order II from 05/26/2010 of 36 rats with behavioral testing beginning on 07/05/2010." Upon information and belief, Zhu never performed the behavioral testing, as he claimed, beginning on July 5, 2010. *See* Part V(B), *supra*, at ¶ 56. Therefore, any data files produced by Zhu purportedly obtained from this alleged experiment are falsified and/or fabricated.

133. As described in Paragraph 125, the Original Allegation sets forth a reasonable basis for concluding that Zhu committed plagiarism under the Regulations.

134. At worst, the March 12, 2015 interview sets forth a reasonable basis for concluding that Zhu committed falsification and/or fabrication under the Regulations.

135. The Original Allegation specifically states that the identified research misconduct involves PHS supported research.

136. The facts obtained during USC's inquiry, as discussed in Paragraphs 124 through 132, indicate that the Original Allegation may have substance.

137. Despite the clear factual support for conducting an investigation into Zhu's research misconduct, USC arbitrarily concluded that an investigation into the Original Allegation was not warranted. USC reached this conclusion without reviewing all relevant information, including the raw data.

(c) ORI prompted another inquiry into the allegations of research misconduct against Zhu.

138. Due to the obvious conflicts of interest involved in the USC inquiry into Jun Zhu's research misconduct, Drs. Booze and Mactutus contacted ORI with their concerns in a letter dated May 4, 2015. In this letter, Drs. Booze and Mactutus outlined Jun Zhu's research misconduct and the deficiencies in the USC inquiry.

139. Drs. Booze and Mactutus followed up with an additional letter to ORI on July 14, 2015 that identified several additional instances of research misconduct by Zhu. Drs. Booze and Mactutus also notified Tommy Coggins and Kim Creek of these allegations as well.

140. In response to Drs. Booze and Mactutus' letter, ORI notified USC shortly thereafter that USC's first inquiry into the Jun Zhu research misconduct allegations was not satisfactorily completed due to the presence of conflicts of interest and directed USC to conduct a proper inquiry under the PHS Regulations.

(d) USC summarily dismissed the second allegation of research misconduct against Zhu without conducting an inquiry.

141. As described previously in Paragraph 138, Drs. Booze and Mactutus identified additional instances of research misconduct after filing their first allegation. Upon identifying these additional instances of falsification and/or fabrication by Jun Zhu, they notified USC administrators Tommy Coggins and Dr. Kim Creek.

142. Creek, in his capacity as Vice-Chair of Drug Discovery and Biomedical Sciences at the USC College of Pharmacy, summarily and arbitrarily concluded that no inquiry would be conducted on the second allegation of research misconduct involving Jun Zhu.

143. Creek's wife is the lead PI on the IMBRE Grant, which is affected by the Zhu research misconduct.

144. It is the understanding of Drs. Booze and Mactutus that USC did not document the second allegation of research misconduct or any aspect of its decision not to conduct an inquiry as required under the PHS Regulations and its own USC Policy.

(e) USC conducts a second defective inquiry into Zhu's research misconduct.

145. Despite being directed by ORI to conduct a proper inquiry, USC again appointed researchers and administrators with conflicts of interest to conduct the inquiry. These individuals included Drs. Twiss and Fadel, both of whom are collaborators with Zhu.

146. Despite being previously notified by Drs. Mactutus and Booze that their laboratory alone possessed the raw data for Zhu's experiments, the USC investigators went to Zhu himself and asked for the raw data for his experiments.

147. Zhu provided the investigators data that he claimed came from the experiments described in his publications.

148. This data provided by Zhu was not contemporaneous, legitimate raw data for his experiments – no experiments were conducted on the days that he claimed, and Dr. Mactutus alone would have had such data if it existed.

149. At the conclusion of its second "inquiry," USC administrators again cleared Zhu of wrongdoing, while criticizing him for poor statistical practices.

(e) USC made false certifications of compliance with research misconduct policy in grant applications and progress reports.

150. USC expressly certifies compliance with a variety of administrative policies and regulations in order to obtain NIH grants. This certification is made by an institutional official on every grant application and progress report.

151. This express certification includes a certification on the part of USC that it is in compliance with all PHS Regulations governing research misconduct, that it will foster an environment of research integrity, will forthrightly address allegations of research misconduct, conduct inquiries and investigations promptly and thoroughly in accordance with PHS

Regulations, notify ORI and external funding sources in special circumstances, and safeguard PHS funds.

152. USC's express certifications that it was in compliance with these requirements were false when made and remain false to this day.

(f) USC eliminates Drs. Booze and Mactutus' laboratory space.

153. In the Fall and Winter of 2015/2016, after making these allegations of research misconduct against Zhu and complaining to ORI of the deficient USC response, Drs. Booze and Mactutus learned that USC was eliminating a significant amount of their laboratory space.

154. The loss of laboratory space is particularly significant to Drs. Booze and Mactutus because they are losing their laboratory space that is licensed for experiments involving radiation. Without this laboratory space, they are unable to conduct some of the experiments envisioned in their current federal grant funding, and they will be further prevented from applying for further federal grant funding within their fields of study.

155. Upon information and belief, USC's decision to eliminate Drs. Booze and Mactutus' laboratory space is retaliatory and stems at least in part from their actions in reporting Zhu's research misconduct and USC's deficient institutional response.

E. Knowledge/Scienter

156. Jun Zhu and USC knowingly submitted false claims for payment in connection with NIH and NSF grants because Zhu and USC (1) actually knew that the research results were falsified and/or fabricated, (2) acted in deliberate ignorance as to the truth or falsity of the research results, and/or (3) acted with reckless disregard as to the truth of the research results in placing them in grant applications and progress reports.

157. USC, through its administrators, knew that it was not conducting its inquiries into Zhu's research misconduct in accordance with its own USC Policy or the PHS Regulations.

158. USC also had actual knowledge that its express certifications to the NIH that it was in compliance with PHS regulations was false when made. Alternatively, USC acted in deliberate ignorance as to the truth of its express certification to the NIH and/or acted with reckless disregard as to the truth of its express certification.

F. Materiality

159. The falsified and/or fabricated research results contained in the grant applications and progress reports described above are material because they are capable of influencing the NIH's funding decision. Preliminary data are required for NIH grant applications, and progress reports are required per the NIH Grant Policy Statement to include all scientific results of the grants, both positive and negative.

160. The false express certifications made by USC in its grant applications and progress reports are material to the NIH's funding decision because it is capable of influencing the NIH funding decision. These express certifications are required to be made as a prerequisite of any NIH funding.

VI. Causes of Action

Count One: False or Fraudulent Claims in Grant Applications and Grant Progress Reports; 31 U.S.C. § 3729(a)(1)(A)

161. Relators incorporate each of the paragraphs 1-160 as if fully set forth in Count One.

162. The United States seeks relief against Defendants under the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

163. From 2009 to the present, Zhu knowingly caused to be presented false or fraudulent claims for payments in grant applications or grant progress reports submitted to the NIH with respect to grant numbers: R01 DA035714; R03 DA024275; R03 DA026721; P20 GM103641; and P20 GM103499.

164. As a result of Zhu's research misconduct and fraud, USC knowingly presented false or fraudulent claims for payments in grant applications and grant progress reports submitted to the NIH with respect to grant numbers: R01 DA035714; R03 DA024275; R03 DA026721; P20 GM103641; and P20 GM103499.

165. The false or fraudulent statements of research results, publications that included false, fabricated, and/or fraudulent statements of research results, and false certifications were material to the NIH's decision to fund the grants.

166. As a result of the false or fraudulent claims, the United States sustained direct and substantial monetary damages, in the amount of the federal funds paid to USC under grant numbers: R01 DA035714; R03 DA024275; R03 DA026721; P20 GM103641; and P20 GM103499. These damages include, at a minimum, the total cost of these grants paid since 2009, an amount exceeding $43,390,747.

167. The false or fraudulent claims proximately caused additional damages and deprived other researchers of access to scarce NIH funds.

168. By reason of the false or fraudulent claims, the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus civil penalties for each violation.

Count Two: False Records or Statements in Grant Applications, Grant Progress Reports, and Institutional Assurance and Annual Reports; 31 U.S.C. § 3729(a)(1)(B)

169. Relators incorporate each of the paragraphs 1-168 as if fully set forth in Count Two.

170. The United States seeks relief against Defendants under the False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

171. Defendants knowingly made, used, or caused to be made or used, false records or statements material to false or fraudulent claims for payments, that were made in grant applications and grant progress reports submitted to the NIH with respect to grant numbers: R01 DA035714; R03 DA024275; R03 DA026721; P20 GM103641; and P20 GM103499.

172. The false records or statements include: (i) false statements of research results made in grant applications or grant progress reports; (ii) false publications reported in the grant applications or grant progress reports; (iii) false certifications in the grant applications or grant progress reports; (iv) the grant applications and grant progress reports, as false records; and (v) false certifications in the Institutional Assurance and Annual Reports.

173. The false records or statements were material to the NIH's decision to fund the grants.

174. As a result of the false or fraudulent claims, the United States sustained direct and substantial monetary damages, in the amount of the federal funds paid to USC under grant numbers: R01 DA035714; R03 DA024275; R03 DA026721; P20 GM103641; and P20 GM103499. These da mages include, at a minimum, the total cost of these grants paid since 2009, an amount exceeding $43,390,747.

175. The false records or statements proximately caused additional damages and deprived other researchers of access to scarce NIH funds.

176. By reason of the false or fraudulent claims, the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus civil penalties for each violation.

Count Three: False or Fraudulent Claims in Grant Applications and Grant Progress Reports with Respect to USC's Assurance Status; 31 U.S.C. § 3729(a)(1)(A)

177. Relators incorporate each of the paragraphs 1-176 as if fully set forth in Count Three.

178. The United States seeks relief against Defendants under the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

179. USC and Coggins falsely certified USC's compliance with its assurances to the United States with respect to the Regulations for some or all of the calendar years from 2009 to present.

180. USC and Coggins made the false certifications knowingly.

181. During some or all of those years, USC knowingly failed to report to ORI allegations of possible research misconduct, failed to conduct warranted inquiries and investigations into the allegations, and failed to conduct the inquiries in accordance with its policy governing research misconduct and the Regulations.

182. During those years, USC knowingly failed to foster an appropriate research environment as required by 42 C.F.R. Part 93.

183. During those years, USC knowingly failed to otherwise comply with the Regulations.

184. During those years, USC knowingly failed to forthrightly deal with possible research misconduct as required by 42 C.F.R. Part 93.

185. As a result, USC and Coggins knowingly made false or fraudulent claims for payments in all grant applications and all grant progress reports submitted to the NIH after the date on which USC failed to comply with its assurances to the United States with respect to the Regulations.

186. All applications for PHS funding and progress reports to continue PHS funding during these years were false claims for payment because of the false express certification contained within each claim for payment.

Count Four: False Records or Statements with Respect to USC's Assurance Status; 31 U.S.C. § 3729(a)(1)(B)

187. Relators incorporate each of the paragraphs 1-186 as if fully set forth in Count Four.

188. The United States seeks relief against Defendants under the False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

189. USC and Coggins falsely certified USC's compliance with its assurances to the United States with respect to the Regulations for some or all of the calendar years from 2009 to present.

190. USC made the false certifications knowingly.

191. During some or all of those years, USC knowingly failed to report to ORI allegations of possible research misconduct, failed to conduct warranted inquiries and investigations into the allegations, and failed to conduct the inquiries in accordance with its policy governing research misconduct and the Regulations.

192. During those years, USC knowingly failed to foster an appropriate research environment as required by 42 C.F.R. Part 93.

193. During those years, USC knowingly failed to otherwise comply with the Regulations.

194. During those years, USC knowingly failed to forthrightly deal with possible research misconduct as required by 42 C.F.R. Part 93.

195. As a result, USC and Coggins knowingly made false or fraudulent records material to false claims for payment in all grant applications and all grant progress reports submitted to the NIH after the date on which USC failed to comply with its assurances to the United States with respect to the Regulations.

196. All applications for PHS funding and progress reports to continue PHS funding during these years were false records material to false claims for payment due to the false express certification contained within each claim for payment.

Count Five: Reverse False Claims; 31 U.S.C. § 3729(a)(1)(G)

197. Relators incorporate each of the paragraphs 1-196 as if fully set forth in Count Five.

198. The United States seeks relief against Defendants under the False Claims Act, 31 U.S.C. § 3729(a)(1)(G).

199. USC and Zhu had an obligation to repay grant funds procured through falsified and fabricated research per the NIH Grants Policy Statement.

200. USC and Zhu made false statements and/or sought to improperly avoid or decrease their obligation to repay grant funds to NIH.

201. USC and Zhu made false statements and/or sought to improperly avoid or decrease their obligation to repay grant funds knowingly.

202. By reason of the defendants' false statements and actions to improperly avoid or decrease their obligation to repay grant funds, the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus civil penalties for each violation.

Count Six: Retaliation; 31 U.S.C. § 3730(h)

203. Relators incorporate each of the paragraphs 1-202 as if fully set forth in Count Six.

204. Relators Booze and Mactutus engaged in protected activity when they complained to ORI and the USC Administration with regard to Zhu's research misconduct and the deficiency of the USC response.

205. Relators Booze and Mactutus engaged in protected activity in order to stop or prevent one or more FCA violations.

206. USC discriminated against Relators Booze and Mactutus in the terms and conditions of their employment as a result of their protected activity.

207. Relators Booze and Mactutus' complaints to ORI and USC administrators and their efforts to stop the FCA violations outlined above were the cause, or contributed to, USC's decision to reduce and/or eliminate their laboratory space.

208. USC is retaliating against Relators Booze and Mactutus by taking laboratory space from them. The loss of this laboratory space, particularly the specialized facilities, will directly impact the relators' ability to apply for federal grants and continue to participate in existing federal grants.

209. Relators Booze and Mactutus suffered and continue to suffer damages to include loss of income, reputational damage, emotional distress, inconvenience, mental anguish, and loss of enjoyment of life.

VII. Prayer for Relief

WHEREFORE, Relators, on behalf of the United States, pray that judgment be entered in their favor and against Defendants as follows:

1. That Defendants pay the United States triple the amount of its damages to be determined at trial, plus civil penalties of up to $11,000 for each false claim, statement, or record;

2. That the Relators be awarded all reasonable attorneys' fees and costs, pursuant to 31 U.S.C. § 3730(d)(1) and/or 31 U.S.C. § 3730(d)(2);

3. That in the event that the United States proceeds with this action, the Relators, for bringing this action, be awarded an amount of at least fifteen percent but not more than twenty five percent of the proceeds of any award or the settlement of the claims;

4. That in the event that the United States does not proceed with this action, the Relators be awarded an amount that the Court decides is reasonable for collecting the civil penalty and damages, which shall not be less than twenty five percent nor more than thirty percent of the proceeds of any award or settlement;

5. That the Relators be awarded the maximum amount allowed pursuant to 31 US.C. § 3730(d);

6. That the Relators be awarded pre-judgment and post-judgment interest; and

7. The Court award such other and further relief as is just, equitable, and proper;

Relators request a jury on all issues so triable.

April 22, 2016

Respectfully submitted,

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By: _____

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